

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Pharmacy Compounding Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

DMB

Display Date	6-28-00
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Certifier	SN Reese

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Pharmacy Compounding Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on July 13 and 14, 2000, 8:30 a.m. to 5 p.m.

Location: CDER Advisory Committee conference room 1066, 5630 Fishers Lane, Rockville, MD.

Contact Person: Jayne E. Peterson or Tony A. Slater, Jr., Center for Drug Evaluation and Research (CDER) (HFD-21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7001, e-mail: PETERSONJ@CDER.FDA.GOV, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12440. Please call the Information Line for up-to-date information on this meeting.

Agenda: On July 13, 2000, the committee will review five drug products for inclusion on a list of drug products that cannot be compounded because they have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective (see 21 CFR 216.24 (64 FR 10944, March 8, 1999)) whereby FDA amended its regulations to include such a list of drug products). In the **Federal Register** of January 4, 2000 (65 FR 256), FDA published a proposed rule amending these regulations to add two drug

products to the list: (1) Aminopyrine (all drug products containing aminopyrine) and (2) astemizole (all drug products containing astemizole). In addition to these two drug products, the committee will review the following three drug products: (1) Grepafloxacin (all drug products containing grepafloxacin), (2) troglitazone (all drug products containing troglitazone), and (3) cisapride (all drug products containing cisapride). Beginning at approximately 10 a.m., and continuing on July 14, 2000, at approximately 8:30 a.m., the committee will discuss and provide FDA with advice about drug products that present demonstrable difficulties for compounding that reasonably demonstrate an adverse effect on the safety or effectiveness of those drug products.

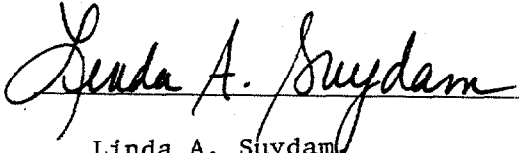
Procedure: Interested persons may present data, information, or views, orally or in writing on issues pending before the committee. Written submissions may be made to the contact person by July 3, 2000. On July 13, 2000, oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. On July 14, 2000, oral presentations from the public will be scheduled between approximately 8:30 a.m. and 9:30 a.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July 3, 2000, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

FDA regrets that it was unable to publish this notice 15 days prior to the July 13 and 14, 2000, Pharmacy Compounding Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Pharmacy Compounding Advisory Compounding Advisory Committee meeting were available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app.

2).

Dated: 6/20/00
June 20, 2000



Linda A. Suydam
Senior Associate Commissioner.

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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